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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,755	03/29/2006	Hiroshi Fukushima	NPR-185	3987
20374 7590 04/22/2009 KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202				
EXAMINER				
MARCETICH, ADAM M				
ART UNIT		PAPER NUMBER		
3761				
MAIL DATE		DELIVERY MODE		
04/22/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/573,755

**Applicant(s)**

FUKUSHIMA ET AL.

**Examiner**

Adam Marcetich

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Priority***

1. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Japan 2003-340851, filed on 30 September 2003 has been received. A priority date of 30 September 2003 is given to claims 1-4,7 and 10-12.

***35 USC § 112, 6<sup>th</sup> Paragraph***

2. Applicant has amended the claims from "separation display means" to "separation display section," and removed the language "means" from corresponding claims. Therefore 35 USC 112, 6<sup>th</sup> paragraph is no longer invoked.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-4, 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sperko; William A. et al. (US 5910138) in view of Hustad et al. (US 5103979) in view of Brochman (US 3923198).
6. Regarding claims 1 and 7, Sperko discloses a medical container (col. 3, lines 21-37, col. 9, lines 60-67, Figs. 1, 2, container 10) comprising:
  - a separable partition wall section which is formed by heat-welding or bonding parts of container outer members opposed to each other (col. 7, lines 34-41, col. 17, lines 14-22, Figs. 1, 2, peelable seals 25, 26 formed by heated bars); and
  - the partition wall section being at least partially blocked or filled by contents in the medical container when the partition wall section is separated (col. 7, lines 54-61, Figs. 1, 2, seals 25, 26 ruptured to allow mixing). Examiner interprets the mixing and flow of medication between the spaces of seals 25 and 26 as at least partially blocking a partition wall section, since particulate matter moves into the space between these seals during mixing (col. 8, lines 19-31, especially lines 28-31). Sperko discloses the invention substantially as claimed, see above. However, Sperko lacks a separation display section as claimed [claim 1]. Hustad discloses a package for hermetically sealing consumable products (col. 1, lines 8-15, col. 4, lines 9-28, especially lines 16-22), further comprising:
    - a separation display section (col. 4, lines 9-28, especially lines 16-22, col. 5, lines 40-55, Figs. 5-6, peel seal area 25);

said separation display section being visible from outside the container outer member opposed to the container outer member on which the separation display section is provided, prior to separation of the partition wall section. (col. 6, lines 25-33, Figs. 10-11, transparent front panel 41 and opaque rear panel 42). To clarify, an opaque rear panel allows viewing only from a side opposed to the container outer member on which separation display means is provided.

One would be motivated to modify Sperko with the separation display section as taught by Hustad to ensure that mixing has occurred since Sperko calls for a transparent material that allows a user to inspect contents visually (col. 8, lines 19-31, especially lines 28-31. in other words, Sperko points out the importance of inspecting the contents of a mixing bag before dispensing to a patient. Hustad provides the advantage of indicating upon even casual examination when a package has been opened due to either tampering or normal use (col. 4, lines 9-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sperko as discussed with the separation display means as taught by Hustad in order to allow quick examination of package.

Sperko in view of Hustad discloses the invention substantially as claimed, see above. However, Sperko in view of Hustad discloses only a separation display section printed directly on a separation display means (Hustad, col. 5, lines 7-20, peel seal area 25 and peel seal message indicia 27 formed by heat seal bar). Additionally, Sperko and Hustad lacks printing on an outer surface as claimed [claims 1 and 7]. To restate, Sperko and Hustad are silent regarding a separation display section provided or printed

on an outer surface, and also lack a film as claimed [claim 7]. Brochman discloses a tape closure system having an opacifying layer and obscuring effect (col. 1, lines 44-46, 53-62, col. 3, lines 37-43), further comprising separation display means provided on an outer surface of a container (col. 4, lines 10-19, Fig. 1, indicator strip 16). Examiner interprets the limitation of "printing" on one of the container outer members broadly to include indicator strip 16 of Brochman as provided outside and bonded to layer 20. Brochman provides the advantage of simultaneously hermetically sealing an aperture and providing tamper indication (col. 4, lines 10-19, film 26 and adhesive 28 sealing aperture 12). This is valuable in the present invention since a bag containing separate medical products often require sealing an edge during manufacture. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sperko in view of Hustad as discussed with the separation display means as taught by Brochman in order to simultaneously seal an opening and provide tamper indication.

7. Regarding claims 2, 3, 10 and 11, Sperko discloses a medical container comprising:

[2, 10] outer members made of synthetic resin film (col. 8, lines 10-18, especially line 18, polymer films); and

[3, 11] wherein the medical container is a multiple-chamber container which has a separable partition wall section formed by heat-welding parts of films opposed to each other and has a plurality of chambers partitioned by the partition wall (col. 17, lines 14-

22, Figs. 1, 2, peelable seals 25, 26 formed by heated bars and separating container into a plurality of chambers).

8. Regarding claims 4 and 12, Sperko discloses the invention substantially as claimed, see above. However, Sperko lacks separation display means as claimed [claims 4 and 12]. Hustad discloses:

a separation display section having a symbol display section (col. 6, lines 25-33, Figs. 10-11, message information 45); and

a symbol covering section provided outside the symbol display section (col. 6, lines 25-33, Figs. 10-11, rear panel 42); and

the symbol covering section covers the symbol display section such that the symbol display section cannot be visually recognized from outside the container outer member on which the separation display section is provided (col. 6, lines 25-33, Figs. 10-11, rear panel 42 disclosed as opaque and therefore preventing the symbol display section from being visually recognized from outside the container outer member on which the separation display means is provided). Hustad provides the advantage of allowing even minor openings of a peel seal to be detected (col. 6, lines 18-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sperko as discussed with the separation display means as taught by Hustad in order to detect even minor openings of a peel seal.

***Response to Amendment***

9. Rejection of claim 8 under 35 USC § 101 and 112, and objection to claim 3 for minor informalities applied in the Office Action dated 10 September 2008 are withdrawn in view of the amendments filed 10 February 2009.

10. Applicant's amendments filed 10 February 2009 have replaced the language "means for" with "section" throughout the claims, therefore 35 USC § 112, 6th Paragraph is no longer invoked for any claims.

***Response to Arguments***

11. Applicant's arguments, see p. 6-11 filed 10 February 2009 with respect to the rejection(s) of claim(s) 1-4,7 and 10-12 under 35 USC § 103 over Inuzuka, Hustad and Brochman have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Sperko, Hustad and Brochman.

12. Applicant correctly notes that the Office intended to cite Hustad '979 (US 5,103,979) instead of Hustad '664 (US 5,064,664). Applicant reasons that a rejection over Hustad '979 should not be made Final since this will constitute a new ground of rejection not necessitated by the above amendments to the claims. The Examiner regrets the typographical error that resulted in the citation of the incorrect document in the body of the non-final rejection. However, the Applicant clearly understood the art the Examiner intended to apply, and referred to the correct reference extensively in the remarks. Accordingly, it is the position of the Examiner that the typographical error in



the non-final rejection did not disadvantage the Applicant with regards to prosecution history. Examiner notes that claims 1-4,7 and 10-12 have been rejected over Sperko in view of Hustad in view of Brochman (a new combination of references) as necessitated by amendment. To clarify, Applicant has amended the independent claims 1 and 7, and Examiner has accordingly applied new art, namely Sperko.

13. Applicant points out that the limitation in the claims of the "separation display section being at least partially blocked by contents in the medical container when the partition wall section is separated" is supported by the description in paragraphs [0040] and [0054].

14. Applicant contends that Hustad lacks a separation display section provided on an outer surface since the separation display section of Hustad (i.e., "message information") must be printed on an inner surface so as to be visible from outside the container outer member opposed to the container outer member on which the separation display means is provided prior to separation. Examiner notes that Brochman teaches an example of printing or placing a separation display section on an outer surface in the new grounds of rejection.

15. Applicant notes that the indicia of Brochman appear after the closure has been flexed, contrary to Applicant's indicia, which are obscured after opening. Examiner notes that Hustad teaches examples of indicia that alternately appear or disappear upon opening. In other words, Hustad teaches a separation display section corresponding to Applicant's. Examiner looks to Brochman as an example of teaching printing on an outer surface.

16. Applicant asserts that none of Inuzuka, Hustad or Brochman disclose or suggest a separation display section that is at least partially blocked by contents in the medical container when the partition wall section is separated as required by the present claims. Examiner points out that Sperko discloses particulate matter filling the space between seals 25 and 26 when mixing contents of container 10; see discussion of claim 1 above.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. May; Timothy J. US 5492411

19. Webb; Nicholas J. et al. US 5727684

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761, 21 April 2009